NOV 2 1 2003

K032992

10. 510(k) SUMMARY OF INFORMATION RESPECTING SAFETY AND EFFECTIVENESS

A. Name and Address of Submitter

Company Name and Address:	Biotech Atlantic, Inc. 6 Industrial Way West Eatontown, NJ 07724
Telephone:	732-389-4789
Fax:	732-389-3837
Contact Person:	Francis Ling Deng

B. Device Name

Proprietary Name:	UniMark® Home Pregnancy Test Device
Common Name:	hCG Pregnancy Test
Classification:	Human Chorionic Gonadotropin (hCG) Test System

C. Legally Marketed Devices

UniMark® hCG Pregnancy Test (device and strip), K941090

UniMark® Midstream Pregnancy Test Stick, K960174

D. Device description

The UniMark® Home Pregnancy Test Device is a colored solid-phase Chromatographic Immunoassay (CIA) for qualitative detection of elevated levels of hCG in urine for the early pregnancy diagnosis. It is a home use, rapid, visual, one step pregnancy screening test.

Human Chorionic Gonadotropin (hCG) is a glycoprotein hormone synthesized by the placenta and released in blood and urine soon after the implantation of a fertilized ovum in the chorionic tissue. HCG is the principal signal and specific marker of the pregnancy. During the test, the specimen is sucked up through the conjugate pad. The hCG in the specimen is captured by the mouse anti-beta hCG antibodies conjugated to colloidal gold particles. The mixture moves up the membrane by capillary action and is captured by the immobilized goat anti-hCG antibodies at the test zone of the membrane to form an antibody-hCG-gold conjugate complex. An appearance of a purple band in the test zone is the positive result, which indicates the presence of an hCG and suggests a pregnancy. Absence of this band, on the other hand, displays a

negative result, i.e. no detectable hCG in the specimen. The appearance of the purple band in the control window demonstrates proper performance and validity of the reactive reagent.

E. Intended Use

The UniMark® Home Pregnancy Test Device is intended for the qualitative measurement of human Chorionic Gonadotropin (hCG) in urine as a home use screening test for pregnancy.

F. Comparison with Predicate Device

A summary comparison of the features of UniMark® Home Pregnancy Test Device, UniMark® hCG Pregnancy Test Device, UniMark® Midstream Pregnancy Test Stick are provided in Table 1 of section 9-A.

G. Performance Data

(1) Non-Clinical Tests

The tests were done for UniMark® hCG Pregnancy Test (K941090) and summarized in the Performance Characteristics of the UniMark® hCG Pregnancy Test Device. Please see the package insert of UniMark® hCG Pregnancy Test Device (***Attachment D,*** page 20 - 22) and the following summarization.

PERFORMANCE CHARACTERISTICS

Sensitivity
UniMark® hCG pregnancy test device detects urinary hCG concentrations of 25 mIU/ml or greater (WHO 3rd IS 75/537).

Accuracy
364 randomly selected urine specimen, 189 positive and 175 negative, were analyzed by the UniMark® hCG test in parallel with a commercially available quantitative visual hCG test. The result shows complete agreement.

Specificity
During the specificity (cross-reactivity) study, the negative results were obtained from all of the UniMark® hCG pregnancy test device assayed with 200 mIU/ml hLH, 1000 mIU/ml hFSH and 1000 μIU/ml hTSH.

Interference Testing
The amount of the following substances added to the urine specimen will not interfere with UniMark® hCG pregnancy test.

Acetaminophen	20	mg/dl
Acetylsalicylic Acid	20	mg/dl

Ascorbic Acid	20	mg/dl
Atropine	20	mg/dl
Caffeine	20	mg/dl
Gentisic Acid	20	mg/dl
Glucose	2000	mg/dl
Hemoglobin	1	mg/dl
Protein	2000	mg/dl
PH	5 to 9	

(2) Consumer Study

The UniMark® Home Pregnancy Test Device was evaluated in a consumer study of 100 home users selected on a random basis as they presented themselves at the offices or labs of the assigned organizers in central New Jersey and New York City. The home users represented a diverse ages, backgrounds, and educational levels.

Urine specimens from non-pregnant women were examined and mixed as an hCG-free specimen. The specimens were split into 4 fractions and spiked with hCG to the concentrations of 0, 20 (20% lower than 25 mIU/ml, the sensitivity level), 30 (20% higher than 25 mIU/ml) and 1000 mIU/ml. Each fraction was further split into dropping bottles. The bottles were labeled with codes. 4 pregnancy devices and one coded control set (0, 20, 30, 1000 mIU/ml) were placed into one bag as one *study-kit*.

The study was explained to the home users by the organizer or lab technician. If the home user agreed to participate, written and verbal instructions on how to perform the test were provided with one *study-kit*. The home user performed the test procedure for each of the four controls and read the results. At the conclusion of the test, each home user was asked to complete and sign a questionnaire to obtain feedback on the test. The home user marked the used devices with a control code and her name. The user test results were observed and verified by the organizer or lab assistant to verify correct interpretation of positive or negative. The form, the control set, and tested devices were put back into the plastic bag as a *back-kit*. All of the *back-kits* were sent back to Biotech Atlantic. The lab technician of Biotech Atlantic subsequently tested the set of coded controls in the *back-kit* from each home user with the professional (predicate) test (UniMark® hCG Pregnancy Test Device) routinely used in the laboratory.

There was 100% correlation between the UniMark® home user and the UniMark® professional test results, as shown in Table 2 below.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 21 2003

Mr. Francis Ling Deng
Chief Executive Officer
Biotech Atlantic, Inc.
Bay F, 6 Industrial Way West
Eatontown, NJ 07724

Re: k032992
Trade/Device Name: UniMark® Home Pregnancy Test Device
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX
Dated: September 23 2003
Received: September 25, 2003

Dear Mr. Deng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

UniMark® Home Pregnancy Test Device

UniMark® Home Pregnancy Test Device (provided as a test strip contained within a plastic test strip holding cassette) is for the rapid and qualitative determination of humane Chorionic Gonadotropin (hCG) in urine. It is intended for consumer use at home.

It is indicated for use in the early detection of pregnancy.

Please DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use ✓

Per 21 CRF 801.109 (Optional Format 1-2-96)

Carol C. Benson for Jean Cooper, DVM
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K032992